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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,593	04/15/2004	Raymond Pratt	109536.159WO1	6645
26694	7590	10/12/2006	EXAMINER	
VENABLE LLP			CHANNAVAJJALA, LAKSHMI SARADA	
P.O. BOX 34385			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20043-9998			1615	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/824,593

**Applicant(s)**

PRATT ET AL.

**Examiner**

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-10-06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of IDS, amendment and remarks all dated 7-10-06 is acknowledged.

Claims 1-24 have been canceled and new claims 25-45 have been added.

A new rejection is made as follows:

#### ***Claim Rejections - 35 USC § 103***

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,895,841 to Sugimoto et al in view of each of the Iga (Alcohol and Alcoholism, 2001) or Hikida et al (PNAS 2003), each of them submitted on PTO-1449.

Instant claims are directed to a method of treating substance abuse in a patient in need of comprising administering a therapeutically effective amount of donepezil or the compound of claim 43.

Sugimoto teaches the compounds of the instant claims (col. 2-3, in particular the compounds of col. 3), as also admitted in the instant specification (page 14, lines 11-12). Sugimoto teaches that the compounds described have a strong and highly selective anti-cholinesterase activity, increasing the amount of acetylcholine, exhibiting an excellent effect on a model with represent to disturbance of memory, and having a persistent activity (col. 1). Sugimoto teaches the compounds as useful for treating diseases such as Alzheimer's, Pick's Disease; ataxias etc., but not for treating the claimed substance abuse, as claimed.

Iga studied the effect of donepezil in a patient with Korsakoff's syndrome and reported that the patient suffering from alcohol dependence also suffered from memory

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disturbance, indifference, disorientation (page 353). Upon treatment with donepezil, Iga reported that the patient exhibited signs of improvement in regained memory and cognitive behavior. Iga suggested that the maximum choline esterase inhibition by donepezil is a function of the amount of donepezil, which improves the amnesic symptoms of activating cholinergic transmission.

Hikida reports that acetylcholine esterase inhibitors prevent long-lasting behavioral abnormalities associated with cocaine and morphine addictions (pages 6169 and 6171). Hikida tested the effect of donepezil, a centrally acting acetylcholine esterase inhibitor and observed that the compound strikingly reduces the morphine induced and cocaine induced effects (page 6172 -6173, figure 5D).

Thus, both Iga and Hikida teach the effect of donepezil on the substance dependence such as alcohol and Hikida also suggests that donepezil, a cholinesterase inhibitor, is effective in treating morphine or cocaine induced withdrawal effects. Therefore, it would it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the acetylcholine esterase inhibitors of Sugimoto for treating ethanol induced withdrawal (Iga) or morphine or cocaine addiction (Hikida) and Hikida further suggests that it is the cholinesterase activity of donepezil that is responsible for the treatment. Thus, a skilled artisan would have exhibited to reduce the drug withdrawal symptoms as well as the associated poisoning with the cholinesterase inhibiting compounds of Sugimoto. Further, optimizing the amounts of compounds and administering by appropriate routes depending on the type of substance abuse or

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addiction, patient population involved etc., are within the scope of a skilled artisan because Sugimoto suggests various dosages and routes of administration.

### ***Response to Arguments***

Applicant's arguments filed 7-10-06 have been fully considered but are moot in view of the new rejection applied above.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7-10-06 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

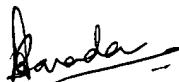
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Primary Examiner  
Art Unit 1615  
October 2, 2006